DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 19, 2014

Acacia, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo MN 55313

Re: K142527
Trade/Device Name: Extension Sets with BD Q-Syte™ Luer Access Split Septum
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 5, 2014
Received: September 8, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142527

Device Name
Extension Sets with BD Q-Syte™ Luer Access Split Septum

Indications for Use *(Describe)*
Non-Power Injectable:

Extension Sets with an attached BD Q-Syte™ Luer Access Split Septum are intended to be used with intravascular catheters to aspirate blood or administer fluids, including medications and blood or blood products. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

Power Injectable:

The Power Injectable Extension Set with an attached BD Q-Syte™ Luer Access Split Septum is intended to be used with intravascular catheters to aspirate blood or administer fluids, including medications and blood or blood products. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

The Power Injectable Extension Set is also indicated for use with intravascular catheters indicated for power injection of contrast media. The Power Injectable Extension Set is suitable for use with power injectors set to a maximum pressure of 325 psi (2,240 kPa) when the BD Q-Syte device is removed and a direct connection is made.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

4. 510(k) Summary

K142527

This 510(k) summary is being submitted in accordance with 21 CFR 807.92.

APPLICANT:	Acacia, Inc.
ADDRESS:	785 Challenger Street Brea, CA 92821
PHONE:	(714) 257-0470
CONTACT PERSON:	Dan Hyun
DATE PREPARED:	July 31, 2014
TRADE NAME:	Extension Set with BD Q-Syte™ Luer Access Split Septum
COMMON NAME:	Intravascular Extension Set
CLASSIFICATION NAME:	Intravascular Administration Set
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	FPA
PREDICATE DEVICES:	MPS Acacia Power Injectable Infusion Set (K090809) MPS Acacia IV Extension Sets (K895367) BD Q-Syte Saf-T PRN Luer Activated Valve (K013621)

Substantially Equivalent To:
The subject Extension Sets with BD Q-Syte™ Luer Access Split Septum are substantially equivalent in intended use, principal of operation and technological characteristics to the MPS Acacia Power Injectable Infusion Set (K090809), MPS Acacia IV Extension Sets (K895367) and BD Q-Syte™ Luer Access Split Septum (K013621).

All materials, manufacturing methods, technological characteristics, and principles of operation are identical to the predicate devices. The reason for this submission is to clarify and align the Indications for Use for all subject devices. The differences in the indications for use are not considered significant since they do not alter the therapeutic effect of the device, which is to provide a conduit for the infusion and withdrawal of fluids through an intravascular catheter.

Description of the Device Subject to Premarket Notification

The Extension Sets with BD Q-Syte™ Luer Access Split Septum consist of a length(s) of flexible non-DEHP PVC clear tubing with a non-removable slide clamp. The devices include an ISO male Luer lock connection with a protection cap on the distal end and an ISO female Luer lock connection on the proximal end(s) with a removable BD Q-Syte device or end cap. The Extension Sets with BD Q-Syte™ Luer Access Split Septum are provided in lengths from 5 in (127 mm) to 21 in (533 mm) with tubing diameters ranging from 0.035 in ID (0.89 mm) x 0.094 in OD (2.40 mm) to 0.110 in ID (2.80 mm) x .161 in OD (4.10 mm). Select Extension Sets include injection sites with a permanently attached BD Q-Syte device. The BD Q-Syte device is a needleless access device provided to aid in reducing the risk of accidental needlestick injuries. The Extension Sets with BD Q-Syte™ Luer Access Split Septum do not contain natural rubber latex.

The Power Injectable Extension Set with BD Q-Syte™ Luer Access Split Septum is suitable for use with power injectors set to a maximum of 325 psi (2,240 kPa) when the BD Q-Syte device is removed and a direct connection is made. This device has a label attached to the tubing stating

"Power Injectable Max 325 PSI".

Indications for Use:

Non-Power Injectable:

Extension Sets with an attached BD Q-Syte™ Luer Access Split Septum are intended to be used with intravascular catheters to aspirate blood or administer fluids, including medications and blood or blood products. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

Power Injectable:

The Power Injectable Extension Set with an attached BD Q-Syte™ Luer Access Split Septum is intended to be used with intravascular catheters to aspirate blood or administer fluids, including medications and blood or blood products. These devices may be used with any patient population with consideration given to the procedure being performed and fluids being infused.

The Power Injectable Extension Set is also indicated for use with intravascular catheters indicated for power injection of contrast media. The Power Injectable Extension Set is suitable for use with power injectors set to a maximum pressure of 325 psi (2,240 kPa) when the BD Q-Syte device is removed and a direct connection is made.

Technical Characteristics:

The subject Extension Sets with BD Q-Syte™ Luer Access Split Septum have the same physical and technical characteristics compared to the currently marketed predicate devices.

Performance Data:

Performance testing was conducted for the predicate devices to demonstrate the integrity and suitability of the device for its intended use. Since the subject devices and currently marketed predicate devices are the same, the results of the predicate testing indicate that the subject Extension Sets with BD Q-Syte™ Luer Access Split Septum are substantially equivalent to the currently marketed predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the subject Extension Sets with BD Q-Syte™ Luer Access Split Septum are determined by Acacia to be substantially equivalent to the currently marketed predicate devices.